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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,456	02/13/2004	Peter Strong	672601-2001	9496

20999 7590 10/05/2007
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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,456	STRONG, PETER	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 35-43* is/are pending in the application.

4a) Of the above claim(s) *4,6,7,10-27,37-43* is/are withdrawn from consideration.

5)☒ Claim(s) *1-3,5,8,9,28-33,35 and 36* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/07 has been entered.

2 Claims 1-33 and 35-43 are pending.

Claims 1-3, 5, 8, 9, 28-33 and 35-36 read on elected species of aeroallergen are being examined.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 5, 8, 9, 28-33 and 35-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata et al. (IDS reference AQ, of record) in view of Clinical Report (Pediatrics, 1997, vol. 100(1):143-152, of record) as is evidenced by the specification of the instant application on p. 13 (newly cited), p.19 (of record), Sigma Chitin powder product sheet (of record) WO 97/20576, newly cited, IDS reference, Kim et al. (J. Dentistry for Children, 2004, vol 71:126-130), newly cited and U.S. Pat. No. 6,080,762, newly cited.

Shibata et al. teach a method of treating an allergy by aeroallergen such as ragweed by administering chitin microparticles (N-acetyl –D-glucosamine) in saline (e.g. a buffer) having diameter of 1-10um into mice (abstract, p. 1320, in particular) and this method is clinically relevant to human therapy (p. 1314, 1320, in particular).

Shibata et al. further teach prophylactic effects of chitin administration, ragweed desensitization (p. 1316, in particular) and chitin induces Th1 cytokines (e.g. IFN-g) which down regulate allergic airway inflammation (p. 1318, discussion, in particular).

Claims 31 and 32 are included because the prior art chitin powder has been purchased from Sigma-Aldrich as well as the claimed chitin powder as is evidenced by the specification of the instant application p. 19. The source of both chitin powder is crab shell and prepared by art-recognized method such as milling.

Shibata et al. do not teach intranasal/nasal administration of chitin microparticles as in claim 1.

However, Clinical Report teaches that nasal /intranasal administration is a well recognized route of administration for delivering drugs in allergy treatment such as corticosteroid or antihistamine and nasal musosal surface provides a rapid and relatively painless drug absorption resulting in rapid central nervous system effect and improve bioavailability (p.5-7, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ intranasal or nasal delivery method in allergy treatment as taught by the Clinical Report in the method of treating allergy as taught by Shibata et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the Clinical Report teaches that the nasal/intranasal method of delivering drugs in allergy treatment provides rapid and painless drug absorption.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 6/29/07 have been fully considered but they are not persuasive.

Applicant traversed the rejection based on that not all limitations of the claimed invention is taught by the references - the new limitation "wherein the CMP preparation is administered to a patient in a therapeutically effective amount of between 0.01 and 100mg of CMP per kg of body weight" is not taught. Applicant further argues that there is no motivation to combine reference because poorly soluble drug is not suitable for nasal delivery based on Merkus et al. reference.

However, as is evidenced by the specification p. 13 of the instant application, the insoluble chitosan, a chitin derivative is available for nasal administration (WO 97/20576). Therefore, Applicant's argument based on Merkus reference to lack of motivation is not suitable to obviate this rejection.

Moreover, as is evidenced by the '762 patent (newly cited), relative to oral delivery, nasal or lung delivery has considerably high bioavailability and this higher bioavailability adds economic benefits because higher bioavailability translated into lower dose (col. 7-8, in particular). It is well known in the art that the intranasal delivery requires lower dose. Therefore, oral delivery dose taught by the Shibata et al. of 250mg/kg cannot be a standard dose for intranasal delivery. Rather, as is evidenced by Kim et al., (J. Dent Child,m 2004, vol. 71, p. 126-130), single oral dose of 0.7mg/kg is equivalent to 0.3mg/kg intranasal dose (abstract, p. 126, in particular). Given that the nasal dose requires lower dose than oral, 250mg/kg is equivalent to about 100mg/kg. Therefore, the limitation 100mg of CMP per kg of body is taught by the reference. Therefore the combination of reference remains obvious.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
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September 24, 2007

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